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QUIDE® tablets
PIPERACETAZINE

DESCRIPTION: QUIDE (piperacetazine) is a piperidine derivative of phenothiazine.
Piperacetazine has the following chemical designation: 10-{3-[4-(2-Hydroxyethyl)-piperidino] propyl} phenothiazin-2-yl Methyl Ketone.

ACTIONS: The exact mode of action of the phenothiazines is unclear, but drugs of this class produce changes at all levels of the central nervous system, as well as on multiple organ systems.

INDICATIONS: QUIDE is indicated for use in the management of the manifestations of psychotic disorders.

CONTRAINDICATIONS: QUIDE is contraindicated in patients who are comatose or markedly depressed from any cause and in the presence of preexisting thrombocytopenia and other blood dyscrasias, bone marrow depression and in patients with significant liver disease. QUIDE is contraindicated in women who are or may become pregnant since animal reproductive studies adequate to establish safety during pregnancy have not been carried out. QUIDE is contraindicated in patients who have shown hypersensitivity to the drug. Cross sensitivity between phenothiazine derivatives may occur.

WARNING: Like other phenothiazines, QUIDE may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery, especially during the first few days of therapy. Therefore, patients should be cautioned accordingly. Concomitant use with alcohol should be avoided due to the potential additive effect. Patients with known suicidal tendencies should not be given QUIDE except under strict medical supervision.
Use in Children: The use of QUIDE in children under 12 years of age is not recommended because safe conditions for its use have not been established.

PRECAUTIONS: Use with caution in persons who:
1. are receiving barbiturates or narcotics, because of additive effects on central nervous system depression. The dosage of the narcotic or barbiturate should be reduced when given concomitantly with QUIDE (piperacetazine).
2. are receiving atropine or related drugs, because of additive anti-cholinergic effects.
3. have a history of epilepsy, because this drug may lower the convulsive threshold. Adequate anticonvulsant therapy must be maintained concomitantly.
4. are exposed to extreme heat or phosphorous insecticides.
5. have a history of peptic ulcer. Aggravation of preexisting ulcer has occurred.
6. have cardiovascular disease.
7. have respiratory impairment due to acute pulmonary infections or chronic respiratory disorders such as severe asthma or emphysema.

Keep in mind that the antiemetic effect may mask the toxicity of other drugs or obscure the diagnosis of such conditions as intestinal obstruction or brain tumor.
Any sign of blood dyscrasias requires immediate discontinuance of the drug and the institution of appropriate therapy.
The possibility of liver damage, pigmentary retinopathy, lenticular or corneal deposits, and development of irreversible dyskinesias should be kept in mind when patients are on prolonged therapy.

Abrupt Withdrawal: In general, phenothiazines do not produce psychic dependence, but gastritis, nausea and vomiting, dizziness and tremulousness have been reported following abrupt cessation of high-dose therapy. Reports suggest that these symptoms can be reduced if concomitant antiparkinson agents are continued for several weeks after the phenothiazine is withdrawn.

ADVERSE REACTIONS: Not all of the following adverse reactions have been reported with QUIDE (piperacetazine), but pharmacological similarities among various phenothiazine derivatives require that each be considered.

Note: Sudden Death has occasionally been reported in patients who have received phenothiazines. In some cases death was apparently due to cardiac arrest, in others the cause appeared to be asphyxia due to failure of the cough reflex. In some patients the cause could not be determined, nor could it be established that death was due to the phenothiazine.

Drowsiness: May occur particularly during the first or second week, after which it generally disappears. If troublesome, lower the dosage.

Jaundice: Incidence is low. When it occurs (usually between the second and fourth weeks of therapy) it is generally regarded as a sensitivity reaction. The clinical picture resembles infectious hepatitis with laboratory features of obstructive jaundice. It is usually reversible although chronic jaundice has been reported with phenothiazine therapy.

Hematological Disorders: Agranulocytosis, eosinophilia, leukopenia, hemolytic anemia, thrombocytopenia purpura and pancytopenia.

Agranulocytosis: Most cases have occured between the fourth and tenth weeks of therapy. Patients should be watched closely during that period for the sudden appearance of sore throat or other signs of infection. If white blood count and differential show significant cellular depression, discontinue the drug and start appropriate therapy. A slightly lowered white count, however, is not in itself an indication to discontinue the drug.

Cardiovascular: Postural hypotension, tachycardia (especially following rapid increase in dosage), bradycardia, cardiac arrest, faintness and dizziness. Occasionally the hypotensive effect may produce a shock-like condition. In the event a vasoconstrictor is required, levarterenol and phenylephrine are the most suitable. Other pressor agents, including epinephrine, should not be used because a paradoxical further lowering of the blood pressure may ensue. EKG changes, nonspecific, usually reversible, have been observed in some patients receiving phenothiazine tranquilizers. Their relationship to myocardial damage has not been confirmed.

CNS Effects: Neuromuscular (extrapyramidal) Reactions: These are usually dose related and take three forms: (1) pseudoparkinsonism; (2) akathisia; and (3) dystonias (Dystonias include spasms of the neck muscles, extensor rigidity of back muscles, carpopedal spasm, eyes rolled back, convulsions, trismus and swallowing difficulties). These resemble serious neurological disorders but usually subside within 48 hours. Management of the extrapyramidal symptoms, depending upon the type and severity, includes sedation, injectable diphenhydramine, and the use of antiparkinsonism agents. In rare instances, persistent dyskinesias, usually involving the face, tongue and jaw, have been reported to last months, even years, particularly in elderly patients with previous brain damage.
Hyperreflexia has been reported in the newborn when a phenothiazine was used during pregnancy.

Other CNS Effects: Cerebral edema. Abnormality of cerebral spinal fluid proteins. Convulsive seizures, particularly in patients with EEG abnormalities or a history of such disorders. Hyperpyrexia.

Adverse Behavioral Effects: Paradoxical exacerbation of psychotic symptoms.

Allergic Reactions: Urticaria, itching, erythema, photosensitivity (avoid undue exposure to the sun), eczema. Severe reactions include: exfoliative dermatitis (rare); contact dermatitis in nursing personnel administering the drug; asthma; laryngeal edema; angioneurotic edema; and anaphylactoid reactions.

Endocrine Disorders: Lactation and moderate breast engorgement in females and gynecomastia in males on large doses; changes in libido; false-positive pregnancy tests; amenorrhea; hyperglycemia, hypoglycemia, glycosuria.

Autonomic Reactions: Dry mouth, nasal congestion, constipation, adynamic ileus, myosis, mydriasis, urinary retention.

Special Considerations in Long-term Therapy: After prolonged administration of phenothiazines, pigmentation of the skin has occurred chiefly in the exposed areas, especially in females on large doses. Ocular changes consisting of deposition of fine particulate matter in the cornea and lens, progressing in more severe cases to star-shaped lenticular opacities; epithelial keratopathies; pigmentary retinopathy.

Other Adverse Reactions: Increases in appetite and weight; peripheral edema.

DOSAGE AND ADMINISTRATION: Dosage should be individualized, not only initially but during the course of therapy, and the minimal effective dose should always be employed. A starting dosage of 10 mg two to four times daily is recommended for adults. The dose may be increased up to 160 mg daily within a three to five day period. Should side effects occur, dosage should be reduced or discontinued as indicated. For maintenance therapy, up to 160 mg daily in divided doses may be given.

OVERDOSAGE WITH PHENOTHIAZINES:
Manifestations: One of three clinical pictures may be seen.
1. Extreme somnolence; patient can usually be roused with prodding, but if permitted will fall asleep. General condition is usually satisfactory. The skin, though pale, is warm and dry. Slight blood pressure, respiratory and pulse changes may occur but are not problems.
2. Mild to moderate drop in blood pressure (patient may be conscious or unconscious). Skin is markedly gray but warm and dry. Nail beds are pink. Respiration is slow and regular. Pulse is strong but rate slightly increased.
3. Severe hypotension, possibly accompanied by weakness, cyanosis, perspiration, rapid, thready pulse and respiratory depression.

Treatment: Is essentially symptomatic and supportive. Early gastric lavage and intestinal purges may help. Centrally acting emetics may not help because of the possible antiemetic effect of QUIDE (piperacetazine). Give hot tea or coffee. Severe hypotension usually responds to measures described under hypotensive effects (see ADVERSE REACTIONS: **Cardiovascular**). Additional measures include pressure bandages to lower limbs, oxygen and I.V. fluids.
Avoid stimulants that may cause convulsions (e.g., picrotoxin and pentylenetetrazol).
Limited experience with dialysis indicates that it is not helpful.

CAUTION: Federal law prohibits dispensing without prescription.

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Note: Dispense only in light-resistant containers; the coatings on these tablets contain light-sensitive colors.

DOW **DOW PHARMACEUTICALS** The Dow Chemical Company Indianapolis, Indiana

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